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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/845,046 | 04/26/2001 | David M. Cobb | PET-01C | 1454 |

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| EXAMINER | |
|---|---|
| NAJARIAN, LENA | |
| **ART UNIT** | **PAPER NUMBER** |
| 3626 | |

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/845,046 | COBB ET AL. | |
| | Examiner | Art Unit | |
| | Lena Najarian | 3626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 21-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 December 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20020430*; 20020513; 20030326; 20030908
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

*1.* Applicant's election without traverse of Group II (claims 11-20) in the reply filed on October 20, 2005 is acknowledged.

2. Claims 1-10 and 21-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 20, 2005.

### *Drawings*

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "101A" and "101B" at p. 6, lines 2-3 of the specification have been used to designate both immunization product manufacturers and immunization providers. The Examiner suggests Applicant correct the specification to match the drawing (change 101A to 100A and 101B to 100B for the product manufacturers). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: items 109A, 105B, 106B, 103B, 111B, 119B, 115B, 121B, 119C, 115C, 105C, 103C, 121C (Fig. 1). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: item 10A (p. 6, line 9). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date

of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 11-15 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Momich et al. (US 6,335,907 B1).

(A) Referring to claim 11, Momich discloses a system for acquiring data related to a medical product being administered to a patient, comprising (col. 4, lines 18-29 and col. 17, lines 34-41 of Momich):

a container comprising a medical product therein (Fig. 15 and col. 5, lines 9-11 of Momich);

a read/write communications device attached to the container, the read/write device comprising product data including product identification data (col. 1, lines 6-12 and abstract of Momich); and

a reader for obtaining the product data from read/write communications device (col. 6, lines 20-29 and col. 10, lines 45-56 of Momich).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 12, Momich discloses wherein the read-write communications device comprises microchip comprising non-volatile memory storing the product data (col. 17, lines 48-50 of Momich).

(C) Referring to claim 13, Momich discloses a writer for transferring the product data to the read/write communications device (Fig. 22 and col. 7, lines 47-62 of Momich).

(D) Referring to claim 14, Momich discloses wherein the container comprises a unit dose container comprising a dosage of the medical product for administration to only one individual (col. 8, lines 35-39 and col. 4, lines 18-29 of Momich).

(E) Referring to claim 15, Momich discloses a method for acquiring data related to a medical product being administered to a patient, the method comprising (col. 4, lines 18-29 and col. 17, lines 34-41 of Momich):

attaching a communications device to product packaging for the medical product, the communications device comprising non-volatile memory (Fig. 15, col. 5, lines 9-11, and col. 17, lines 48-50 of Momich);

downloading product data to the communications device, the product data comprising product identification data (col. 7, lines 47-62, abstract, and Fig. 22 of Momich);

shipping the medical product for delivery to a provider (col. 8, lines 44-46 and col. 14, lines 39-45 of Momich); and

receiving individual data related to individual patients receiving the medical product, the individual data originating from the provider (col. 4, lines 18-29 and col. 7, line 64 – col. 8, line 8 of Momich).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(F) Referring to claim 18, Momich discloses wherein the product packaging comprises a container comprising the medical product therein (col. 5, lines 9-11 of Momich).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(G) Referring to claim 19, Momich discloses uploading the product data at a provider's location; and administering the medical product to an individual (Fig. 22 and abstract of Momich).

(H) Referring to claim 20, Momich discloses entering individual data related to the individual into a tracking file, and including at least a portion of the product data in the tracking file (col. 15, lines 21-34 of Momich).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Momich et al. (US 6,335,907 B1) in view of Engel et al. (US 2002/0069085 A1).

(A) Referring to claim 16, Momich does not expressly disclose wherein the individual data comprises demographic data associated with respective individual patients.

Engel discloses demographic data associated with respective individual patients (see para. 50 of Engel).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Engel within Momich. The motivation for doing so would have been to include basic and pertinent information about a patient (para. 50 and para. 45 of Engel).

(B) Referring to claim 17, Momich does not disclose wherein the individual data excludes personal information capable of identifying respective individual patients.

Engel discloses wherein the individual data excludes personal information capable of identifying respective individual patients (see para. 37 of Engel).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Engel within Momich. The motivation for doing so would have been to remove personal identifying information to maintain privacy and security (para. 37 of Engel).

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a front loading medical injector and syringe for use therewith (5,997,502).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

In
11-28-05

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER